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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,495	08/14/2006	Paolo Cerasoli	GRT/4865-90	4192

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NIXON & VANDERHYE, PC  
901 NORTH GLEBE ROAD, 11TH FLOOR  
ARLINGTON, VA 22203

EXAMINER
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VU, QUYNH-NHU HOANG

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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07/06/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/586,495	<b>Applicant(s)</b> CERASOLI, PAOLO	
	<b>Examiner</b> QUYNH-NHU H. VU	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11-30 is/are pending in the application.
- 4a) Of the above claim(s) 29 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/4/09</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Response to Amendment***

Amendment filed on 6/4/09 has been entered.

Claims 1-8, 11-28 are present for examination.

Claims 9-10 are cancelled.

Claims 29-30 are withdrawn.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 11-20, 25-26, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Littmann (US 3,157,201) in view of Diaz et al. (US 5,693,021) or Fujii (US 6,485,483, cited from IDS).

Littmann discloses, Figs. 1-5, a device comprising: a container 24, 200 (as know that the valve element 200 is constructed in the same manner as the fluid exchange valve 15 described in Figs. 1-4) provided with a cover 26, 126; the container having a bottom, perimeter walls; an internal chamber 80; at least one connection 28-31 (Fig. 1-4), 101, 102, 204 (Fig. 5) extending from external lateral surface of the container; a rotating platform 23, 90, 99; a pin 21-22 integral with said rotating platform; an actuator 20 for rotation of said pin; at least one closing means 202, 402 having a pointed ended (Fig. 5); a receiving housing 103, 105 for holding the closing means 202, 402; an opening for passage of the closing means being fixed on the rotating platform with the opening turned towards the perimeter walls; a releasing housing 103 or 203; the closing means has undercut portions and is held spring loaded 403 radially inside the releasing housing; a means coupling to connection such as syringe or 404; a reference marks 60, 61,

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not only that, the reference mark as an indicia is very well-known in the art so that the users know the status or location of the rotation of knob handle.

Littmann shows that the connection such as 28-31 (Fig. 1-4), 101, 102, 204 (Fig. 5) connected to syringe or catheter or reservoir. Therefore, a syringe 13 or catheter 14 is considered as a connector between the connection and the container 24, 200. Littman does not show that the connector comprising a sleeve coupled to the connection, said connector comprising a spring abutting between the sleeve and a charging handgrip.

a) Littmann in view of Diaz:

Diaz discloses a connector (catheter exchange syringe 10) comprising: a tubular element 12; a sleeve 22, 20 (Figs. 1-3); wherein the portion of 22 can be coupled to the connection or other device; the connector comprising: a spring 30 abutting between the sleeve and a charging handgrip 66 or 46 (Fig. 1).

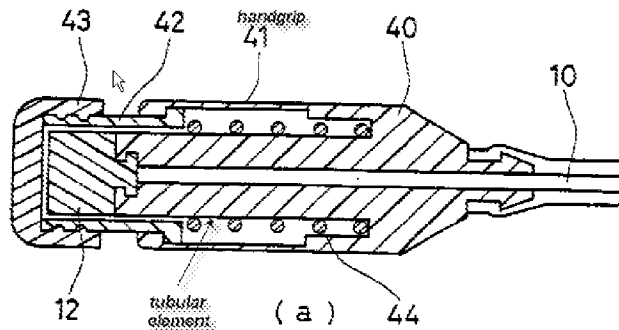
It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Littmann in view of Diaz with a connector (as a syringe with spring), as taught by Diaz, in order to compress or place under tension to act as a source of potential energy for driving the syringe piston portion, while in the unloaded position, the syringe has released its potential energy and has driven the piston through the barrel.

As noted that, The combination between the device of Littmann and Diaz will bring the result such as: when the syringe of Diaz inserted into the connection at interconnection 28-31 (Fig. 1-4), 101, 102, 204 (Fig. 5) of Littmann, from there, the charging handgrip, the sleeve and spring of Diaz being arranged so as to bring the end portion of tubular element of Diaz closer to one of the receiving and releasing housings of Littmann by pushing element 52, then the spring 30 compressed (see Fig. 3 of Diaz).

b) Alternatively, Littmann in view of Fujii:

Fujii discloses similar device in Figs. 1, 14-16 comprising: container with a cover 13; a connection 18 being engaged with a connector 12 comprising a sleeve 12b or 11 coupled to the connection, said connector 12 comprising a spring 44 abutting between the sleeve and a charging handgrip 41; wherein the charging handgrip, sleeve and spring being arranged so as to bring the end point of tubular element closer to one of the receiving and releasing housings.

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It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Littmann in view of Fujii with a connector, as taught by Fujii, in order to compress or place under tension to act as a source of potential energy for securing between the connector and the device.

Claims 1-3, 7-8, 11-20, 25-26, 28 are rejected under 35 U.S.C. 102(b) as being unpatentable over Fuson et al. (US 3,957,082) in view of Diaz et al. (US 5,693,021).

Fuson discloses a container 20 provided with the cover 29; at least one connection 60; a rotating platform 47 (Fig. 3) a pin 45 integral with the rotating platform; an actuator 47 for rotating of the pin; at least one closing means 80; a receiving housing 37, 41; a releasing housing 39; an opening 55 for passage of the closing means being fixed on the rotating platform with the opening turned towards perimeter walls (Figs. 6-8); a reference marks 61, 63, 65, 67, 69, 71.

As known that, the syringe (as a connector) can be connected to the connection 60 or the ports 80 of connecting tube 37, 41. Fuson does not show that the connector comprising a sleeve, spring.

Diaz discloses that a syringe is as a connector and can be inserted into the connecting lines 37, 39, 41 or Fuson; wherein the syringe of Diaz comprising a spring abutting between the sleeve and a charging handgrip, also see the rejection above of Diaz in view of Littmann for more details.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Littmann in view of Diaz with a connector (as a syringe with spring), as

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taught by Diaz, in order to compress or place under tension to act as a source of potential energy for driving the syringe piston portion, while in the unloaded position, the syringe has released its potential energy and has driven the piston through the barrel.

Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Littmann in view of Diaz/Fujii or Fuson in view of Diaz and further in view of Folden (US 5,336,173).

Littmann in view of Diaz/Fujii or Fuson in view of Diaz disclose the invention substantially as claimed. They do not suggest that the receiving or releasing housing contained disinfecting povidone gel; the connection with a fracture membrane.

Folden suggests that the tube can be filled with a sterilizing iodine agent (povidone), col. 5, lines 22+); a scoring line 238 or fracture membrane to separate the tubes (Fig. 5).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Littmann in view of Diaz/Fujii or Fuson in view of Diaz, with disinfecting agent and fracture membrane, as taught by Folden, in order to prevent the growing of bacteria at the connection lines; and the purpose of provide a fracture membrane to separate the tubes easily.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Littmann in view of Diaz/Fujii or Fuson in view of Diaz and further in view of Suzuki et al. (US 2004/0031756).

Littmann in view of Diaz/Fujii or Fuson in view of Diaz disclose the invention substantially as claimed. Littmann in view of Diaz/Fujii or Fuson in view of Diaz do not suggest that a visual means of indication of the number of cycles of dialysis.

Suzuki suggests that a dialysis apparatus comprising a visual means of indication of the number of cycles of dialysis (see Abstract and Fig. 12).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Littmann in view of Diaz/Fujii or Fuson in view of Diaz with a visual indication, as taught by Suzuki, in order to recognize the number of the cycles of peritoneal dialysis.

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***Response to Arguments***

Applicant's arguments with respect to claims 1-8, 11-28 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763